ARC 7903B

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 124.554, the Board of Pharmacy and the Prescription Monitoring Program Advisory Council jointly adopt new Chapter 37, "Iowa Prescription Monitoring Program," Iowa Administrative Code.

Chapter 37 provides for the establishment of a central database program of prescriptions for Schedule II, III, and IV controlled substances prescriptions dispensed in Iowa. Database information regarding the practitioners' patients is available to prescribers and pharmacists (practitioners) to assist the practitioners in determining appropriate pharmaceutical treatment options and to improve the quality of patient care. The rules:

• Define terms used throughout the chapter.

• Identify the dispensers required to submit reports of dispensed prescriptions.

• Identify the records of controlled substance prescriptions to be included in reports from dispensers, and identify the data elements to be included in reported prescription records.

• Establish a schedule of reporting periods and due dates for submission of records of reportable prescriptions for those reporting periods, provide for a variety of methods for submitting dispensing records, and require a pharmacy that did not dispense any prescriptions for reportable controlled substances during a reporting period to submit a report indicating zero records for the period.

• Identify individuals who may obtain information from the program database and the procedures for registering and requesting that information.

• Specify procedures for an individual who is the subject of any database record to report false or erroneous information to the program administrator and procedures in response to such a claim.

• Provide that the Board may charge fees, in limited instances, for information available from the program but specifically exempt dispensers and practitioners from the imposition of fees for reporting to or querying information from the program.

• Establish program record retention periods.

• Address the confidentiality of program and database records and identify prohibited acts relating to the program and program information, providing that a pharmacy or practitioner that knowingly fails to comply with the confidentiality provisions of the law or rules, or a dispenser that fails to comply with reporting requirements, is subject to disciplinary action by the individual's or dispenser's professional license board.

• Provide that a member of the program staff who knowingly fails to comply with the confidentiality provisions of the law or rules is subject to disciplinary action by the Board of Pharmacy.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the April 8, 2009, Iowa Administrative Bulletin as **ARC 7676B**. The Board received written comments regarding the proposed rules from one association representing Iowa pharmacies. The Board scheduled a public hearing regarding the proposed rules. One person appeared at the hearing but presented no written or oral comments.

The adopted rules differ from those published under Notice. Subrule 37.4(2), paragraph "a," has been amended to provide that the director of a health practitioner licensing board or the director's authorized designee may sign and submit a request for PMP information pursuant to the requirements of the paragraph. Subrule 37.4(2), paragraph "b," has been amended to provide that the director of a regulatory agency or the director's authorized designee may sign and submit a request for PMP information pursuant to the requirements of the paragraph. Paragraphs 37.4(2)"a" and "b" now read as follows:

"*a.* A director of a licensing board with jurisdiction over a practitioner, or the director's designee, who seeks access to PMP information for an investigation shall submit to the PMP administrator in a format established by the board a written request via mail, facsimile, or personal delivery. The request shall

be signed by the director or the director's designee and shall be accompanied by an order, subpoena, or other form of legal compulsion establishing that the request is supported by a determination of probable cause.

"*b.* A director of a regulatory agency with jurisdiction over a practitioner or with jurisdiction over a person receiving health care services pursuant to one or more programs provided by the agency, or the director's designee, who seeks access to PMP information for an investigation shall submit to the PMP administrator in a format established by the board a written request via mail, facsimile, or personal delivery. The request shall be signed by the director or the director's designee and shall be accompanied by an order, subpoena, or other form of legal compulsion establishing that the request is supported by a determination of probable cause."

Rule 657—37.7(124) has been amended to identify the individual who will correct, delete, or amend PMP information that has been determined to be in error. Rule 657—37.7(124) now reads as follows:

"**657—37.7(124) Information errors.** Any person who believes that PMP information about that person is false or in error shall submit a written statement to the PMP administrator. The statement shall identify the information the person believes to be false or in error and the reason the individual believes the information to be false or in error. The PMP administrator may examine the information identified in the statement and may request the assistance of the board's compliance staff to determine whether or not the PMP information is accurate. Prior to initiating any action to correct, delete, or amend any PMP information, the PMP administrator shall submit the statement and the resulting report to the patients rights committee for review and approval of the recommended action. If correction, deletion, or amendment of any PMP information is authorized, that action shall be accomplished by the PMP administrator within 72 hours of the committee's decision. The PMP administrator shall respond, in writing, to the person who submitted the statement charging that the PMP information was false or in error. The response shall identify the action approved by the committee."

The rules were approved during the June 2, 2009, regular meeting of the Board of Pharmacy. The rules were approved by the Prescription Monitoring Program Advisory Council by electronic communication between May 27, 2009, and June 2, 2009.

These rules will become effective on August 5, 2009.

These rules are intended to implement Iowa Code sections 124.551 to 124.558 as amended by 2009 Iowa Acts, House File 122.

EDITOR'S NOTE: Pursuant to recommendation of the Administrative Rules Review Committee published in the Iowa Administrative Bulletin, September 10, 1986, the text of these rules [Ch 37] is being omitted. With the exception of the changes noted above, these rules are identical to those published under Notice as **ARC 7676B**, IAB 4/8/09.

[Filed 6/11/09, effective 8/5/09]

[Published 7/1/09]

[For replacement pages for IAC, see IAC Supplement 7/1/09.]